

Cleara Biotech Secures U.S. and Chinese Patent Protection for its p53-Targeting Development Candidate CL04183

Composition of matter patent expected to provide US exclusivity into 2041

Utrecht, Netherlands – 31 August 2026 – Cleara Biotech, a company pioneering a novel approach for the treatment of pan-mutation-p53 cancers by selectively clearing cells in which the p53 protein has become impaired, today announced that the United States Patent and Trademark Office (USPTO) has granted a composition of matter patent (US Patent 12,653,862) covering a broad range of its all-D amino acid cell-penetrating peptides (CPPs), including CL04183, the Company's lead candidate for the treatment of mutant-p53-driven pathologies, including metastatic colorectal, ovarian, breast cancers and non-melanoma skin cancers.

The granted patent provides broad, long-term protection for CL04183 in one of the world's largest markets for medicines, securing a period of exclusivity extending to 2041, with potential for further extension. The Company has also been granted a corresponding composition of matter patent in China (Chinese Patent 202180015708.2) and expects further favorable decisions from patent offices in additional territories currently under examination, such as Japan and Europe, over the coming months.

Peter de Keizer, PhD, Founder and Chief Scientific Officer, commented: *"The grant of the U.S. and Chinese composition of matter patents represents a significant milestone for Cleara Biotech, underscoring the novelty of our science and validating the trust in the translational potential of our pipeline. It reinforces our confidence in the potential of CL04183 to transform the treatment of the many diseases mediated by impaired p53, at a time when we prepare to advance this into clinical development across a range of cancers and other disease areas."*

Jan Krauss, PhD, Partner of SKM-IP, and Cleara's Patent Attorney, added: *"With non-obvious improvements, Cleara's CPPs are optimized around a new Mechanism of Action. These patents secure a broad layer of protection for Cleara's CPPs in major economic territories for years to come."*

"Impairment of p53 drives aggressive, treatment-resistant metastasis—one of the most persistent challenges in cancer medicine today. CL04183 directly targets the vulnerabilities created by p53 impairment, most often caused by point mutations, offering a novel therapeutic path for patients who have exhausted standard-of-care options. Supported by these new patent grants, I look forward to collaborating with the Cleara team to advance CL04183 through clinical development and hopefully bring meaningful benefit to these patients in need," **added Nicholas J. Sarlis, MD, PhD, Chief Medical Officer.**

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About CL04183

CL04183 is Cleara's first-in-class cell-penetrating peptide (CPP) targeting the open conformation of p53, a fundamental cause of p53 functional impairment and a key driver of more than 50% of cancers, as well as other conditions, such as fibrosis and neurodegenerative diseases, all of which represent very large unmet medical needs. It has a unique mechanism of action by selectively inducing apoptosis in cancer cells harboring impaired p53 in a way that is not transcription-dependent and agnostic of the mutation site. CL04183 is highly selective for cells with impaired p53, minimizing off-target effects and representing a potentially breakthrough therapeutic strategy, whether as a single agent or in combination with chemotherapy or targeted therapy with inhibitors of proliferation signaling.

Because the synthetic peptide is composed entirely of D-amino acids, it has favorable drug-like properties, including excellent stability, as well as PK and ADMET attributes. With the completion of GLP-toxicology studies and drug substance CMC, CL04183 has advanced to IND-/CTA-readiness for regulatory filing for a first-in-human clinical study. Cleara is preparing to initiate this clinical trial in 2027.

About Cleara

Cleara Biotech, based in Utrecht, the Netherlands, is a biopharmaceutical company focused on developing synthetic peptide-based therapies against cancer and chronic diseases. Its lead asset CL04183 is directed at cancer cells with high levels of impaired-p53 signaling, including mutant p53.

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